

REMARKS

I. Status of the Claims

Claims 1-12 stand rejected by the Office. Applicants have amended claims 1, 11, and 12 to recite that the hard caramels have reduced water uptake. Support for this amendment can be found in the specification in the Examples, especially on page 11, lines 5-14, and in the general description on page 3, lines 1-8. These amendments add no new matter.

II. Information Disclosure Statement

Applicants submit copies of three references in the attached Information Disclosure Statement. As noted in the Information Disclosure Statement, Applicants provide a copy of U.S. Application No. 09/030,295 to Rapp et al., which sets forth the relevance of non-English language document DE 195 32 396 C2. Applicants respectfully ask that the Office consider the references and provide an initialed PTO/SB/08 indicating that they were considered.

III. Rejection of Claims 1-12 under 35 U.S.C. § 112, ¶1

The Office again rejects claims 1-12 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. (Office Action, page 2.) The entire substance of the Office's rejection is the assertion that "Applicant does not clearly teach what is encompassed by 'improved stability in storage.'" (*Id.*)

Applicants respectfully traverse this rejection for the reasons of record and reiterate that, according to the M.P.E.P., "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed

invention.” M.P.E.P. § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993)). Here the Office fails to address any of the factors set forth in *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988), and discussed in M.P.E.P. § 2164.01(a). These factors must be evaluated before the Office can meet its initial burden.

Nevertheless, solely in an effort to expedite prosecution, Applicants have amended the claims to replace “improved stability in storage” with -- reduced water uptake --, which the specification discloses is an indicia of improved stability in storage. (See, e.g., Specification, page 3, lines 1-8.) The working examples provide methods for assessing whether water uptake is reduced. (See, e.g., Specification, pages 9-13.) The specification, therefore, provides sufficient guidance so that one skilled in the art could determine whether a hard caramel has reduced water uptake without undue experimentation. Accordingly, Applicants respectfully request the Office to withdraw this rejection.

IV. Rejection of Claims 1-12 under 35 U.S.C. § 103(a)

Claims 1-12 stand under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,578,339 to Kunz et al. (“*Kunz*”) and U.S. Patent No. 6,248,386 to Willibald-Ettle et al. (“*Willibald-Ettle*”). (Office Action, page 2.) The Office continues to assert that “in the absence of a showing to the contrary, the amount employed are no matter that [sic] a matter of choice and well-within the skill of the art and at most are deemed optimization.” *Id.* at 3.

The claims of *Kunz* relied upon by the Examiner recite a sweetener (e.g., claim 5) comprising 45% to 60% by weight of 1,1-GPM, or a candy comprising that sweetener

(e.g., claim 21). Claim 8 of *Kunz* further indicates that the sweetener contains small amounts of sorbitol. The Office notes that *Willibald-Ettle* teaches hard caramels comprising 1,1-GPM and sorbitol. The Office states that although “the claims differ [from the teachings of the combination of the references] as to the specific amounts employed,” the amounts employed are “deemed optimization” so that it would have been obvious “to use the claimed percentages in either *Kunz* et al or *Willibald-Ettle* et al because the use and manipulation of both 1,1-GPM and sorbitol are conventional in the production of hard candies such as caramels.” (Office Action, pages 2-3.)

Applicants have previously noted that the claimed invention is for a particular type of candy, a hard caramel, containing not only a specific range of 1,1-GPM, but also 0.5% to 3.5% sorbitol by weight. Thus, the claims do not recite a range for a single variable, but instead recite a particular combination of two variables, 1,1-GPM and sorbitol. Applicants have also pointed out in detail in previous responses that *Kunz* motivates the ordinary artisan *to remove as much sorbitol as possible*, thus teaching away from the claimed invention. The Office, however, has discounted this teaching. Instead, it maintains that “*Kunz* et al and *Willibald-Ettle* et al teach the conventional use of 1,1-GPM and sorbitol in the production of candy/caramel.” (Office Action, page 3.)

Similarly, the Office again points to “the conventional use of 1,1-GPM and sorbitol” in finding that the ordinary artisan would have been motivated by *Kunz* to substitute a sweetener that contains sorbitol in the method of making hard caramels taught by *Willibald-Ettle*. (*Id.* at 4.) This is despite the fact that, as discussed previously, *Kunz* teaches that it is desirable to eliminate sorbitol from the sweetener and neither reference provides any motivation to specifically select the recited ranges of 1,1-

GPM and sorbitol. Thus, Applicants maintain for the reasons set forth in detail in previous responses that the Office has failed to establish a *prima facie* case for rejecting the claims as unpatentable.

It is only after the Office has established a *prima facie* case that Applicants have any obligation to provide evidence of nonobviousness, such as unexpected results. See M.P.E.P. § 2142. Applicants can rebut any presumption of obviousness "by showing '(1) [t]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art.'" M.P.E.P. § 2144.05.III (citing *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 U.S.P.Q.2d 1225, 1228 (Fed. Cir. 2004)).

Here, by teaching that sorbitol should be removed and providing methods for effecting that removal, *Kunz* provides the sort of teaching away that is sufficient to rebut any presumption of obviousness. See *In re Geisler*, 116 F.3d 1465, 1471, 43 U.S.P.Q.2d 1362, 1366 (Fed. Cir. 1997). Further, as discussed previously and elaborated upon below, there is ample evidence of unexpectedly advantageous properties of the claimed hard caramels that would also rebut a *prima facie* case, had the Office established one. See *In re Woodruff*, 919 F.2d 1575, 1578, 16 U.S.P.Q.2d 1934, 1936 (Fed. Cir. 1990).

Applicants have previously discussed the surprising results included in the Specification itself. They also included as part of the November 28, 2005, response a Rule 1.132 Declaration providing and discussing further evidence that hard caramels containing 1,1-GPM and sorbitol in the recited ranges have unexpectedly superior properties that result in improved stability in storage. In the reply to that response,

however, the Office did not address or appear to otherwise consider the data already in the Specification. Further, it dismissed as insufficient the Rule 1.132 Declaration, alleging without any analysis that the Declaration failed to provide a showing commensurate in scope with the broadest claim and that the Declaration failed to analyze the data. (Office Action, page 4.)

As part of the current Request for Reconsideration, Applicants provide a second Rule 1.132 Declaration of Dr. Joerg Kowalczyk to further address the Office's impression that the dependency of storage stability on the content of 1,1-GPM was foreseeable from the teachings of the references. In this Declaration, Dr. Kowalczyk analyzes the results of additional experiments on hard caramels made using concentrations of 1,1-GPM and sorbitol that are within the recited ranges (samples P, Q, T, U) compared to those made with 1,1-GPM concentrations just beyond the recited range (samples O, R, S, V). (*Id.* at ¶9.) The data show that samples made using the claimed concentrations have reduced water uptake. (*Id.* at ¶10 and Table 2.) Reduced water uptake results in improved stability in storage (*id.* at ¶11), which has practical significance because it influences the marketability of the hard caramels (*id.* at ¶7). The unforeseeability of the effect on water uptake of combining specific amount of 1,1-GPM and sorbitol is perhaps easiest to appreciate when one notes that the graph of water uptake shown in Figure 1 is not linear. (*Id.* at ¶13 and Figure 1.) Instead, when either 0.7% or 2.0% sorbitol are combined with varying concentrations of 1,1-GPM, there is an unexpected minimum that appears at the recited range of 1,1-GPM, (*id.* at Figure 1), which, as Dr. Kowalczyk points out, means that this observation is not mere optimization (*id.* at ¶14). This unexpected effect is especially clear with 2.0% sorbitol.

Based on these results, Dr. Kowalczyk, who is an expert in the field, concludes that one could not predict from the teachings of *Kunz* and *Willibald-Ettle* that selecting specific concentrations of 1,1-GPM and sorbitol would result in reduced water uptake and so improve the stability of the hard caramels in storage. (*Id.* at ¶15.)

Thus, even if the Office had established a *prima facie* case of obviousness, the unexpected results shown in the Specification and Rule 1.132 Declarations and the teaching away from the inclusion of sorbitol by *Kunz* would be sufficient to rebut it. Applicants respectfully maintain, however, that the Office failed to establish a *prima facie* case at least because there is no motivation to combine the teachings of the references. For these reasons, Applicants once again respectfully submit that the rejection is in error and request the Office to withdraw it.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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